DEPARTMENT OF HEALTH & HUMAN SERVICES

M3816A

Food and Drug Administration
Seattle District
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COPY

July 16, 1999

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 99-28

Hal Tenoso, President and CEO
Serologicals Corporation
780 Park North Blvd., Suite 110
Clarkston, Georgia 30021-1900

WARNING LETTER

Dear Mr. Tenoso:

During an inspection of the Seramed Biocenter – Lakewood plasmapheresis center located at 10506 Bridgeport Way SW, Tacoma, Washington on June 11 through 17, 1999, our investigator documented violations of Section 501 (a)(2)(B) of the Federal Food, Drug, and Cosmetic Act and Title 21, Code of Federal Regulations (21 CFR), Parts 600-680 as follows:

1. Failure to promptly notify the Director, Office of Compliance, Center for Biologics Evaluation and Research (CBER), of an error in the manufacture of products that may affect the safety, purity, or potency of any product [21 CFR 600.14] in that:

   a. [redacted] of untested Source Plasma were shipped for further manufacture on December 12, 1998, to [redacted] Viral marker test results for the [redacted] units were received by the center on December 16, 1998. The error was discovered by the center on December 18, 1998. As of June 12, 1999, Regulatory Affairs had not submitted an Error and Accident report to CBER.

2. Failure to assure that personnel have the training and experience necessary for the competent performance of their assigned functions [21 CFR 606.20(b)] in that:

   a. On June 11, 1999, two employees were observed to be performing phlebotomies and product collections independently (one of whom was responsible for errors in 3 a and 3 e below) and another employee was observed to perform donor screenings independently, prior to completion of training. The Trainer Guide states that competency is measured at the completion of training by accurate performance of the procedure (documented on the checklists) and by passing the written exam.

b. The "[redacted]- Plasma Collection Checklist" was utilized instead of the "[redacted] Plasma Collection Checklist" for training. This center collects plasma with the [redacted]. The Trainer Guide states to select the checklists that are applicable to the machines used.

3. Failure to maintain and/or follow written standard operating procedures to include all steps to be followed in the collection, processing, storage, and distribution of blood and blood products [21 CFR 606.100(b)] in that:

a. On June 11, 1999, an employee was observed to respond to a "Check AIR, then Δ" machine message by continuing the procedure without visually inspecting the line to ensure it looked free of air bubbles as required in the [redacted] Operator's Manual.

b. Three donors had hemolyzed plasma of a non-transient nature and the donors were not disconnected as required in the [redacted] Operator's Manual. These donors experienced "HB detect," "Red Plasma," and/or "High TMP" machine messages during their donations.

c. Two donors experienced two "Hb Detected" messages while donating due to a change in plasma color and they were not disconnected as required in the [redacted] Operator's Manual.

d. Red blood cell losses due to technical difficulties were not documented in the donor's file as required in Form #u204, Donor Record of Donation. Both were losses due to disposable set changes in response to "Hb detected" machine messages.

e. On June 11, 1999, an employee was observed to palpate the scrubbed site on two donors following the site preparation, contrary to USOP #u4.2, Site Preparation for Invasive Procedure.

f. On June 11, 1999 an employee was observed to begin pheresis on a donor without placing a collection container on the machine and plasma leaked onto the floor. The volume of the spill was not documented and USOP #u15.6, Aseptic Technique, was not followed in that a leak in the collection set occurred yet the bottle was then connected to the leaking port and collection was resumed.

4. Failure to maintain complete and accurate records [21 CFR 606.160(a)(1)] in that the documentation of the destruction of unsuitable units is not always recorded on the Incineration Record. In addition, on one occasion the incorrect unit was listed on the Incineration Record and the unit that was to be destroyed was shipped for manufacture.

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at this facility. It is your responsibility to assure that this facility is in compliance with all requirements of the federal regulations. The investigator issued Form FDA 483 to Sheri L. Newbold, Center Director, at the close of the inspection. A copy is enclosed for your review and action.

We received the June 28, 1999, letter from Richard Devoll, Authorized Official. You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes license suspension and/or revocation, seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps, in addition to those noted in the letter, you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to the Food and Drug Administration, Seattle District Office, Attention: Miriam Burbach, Compliance Officer, at the above mailing address.

Sincerely,

Roger L. Lowell
District Director

Enclosure:
FORM FDA 483

cc: Richard Devoll
Authorized Official
Serologicals Corporation
780 Park North Blvd., Suite 110
Clarkston, Georgia 30021-1900

Sheri L. Newbold
Center Director
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